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BIOSTIM NMS2 INSTRUCTION MANUAL

Please consult your physician or prescribing practitioner for specific instructions regarding the settings of your device. Please read and understand this manual before beginning to use the BioStim[®] NMS².



1. Introduction BioStim® NMS2

1.1 Device Overview

The BioStim NMS2 is a portable electrotherapy device which sends a gentle electrical current to underlying nerves and muscles via electrodes applied to the skin. The device is a NeuroMuscular Stimulator (NMS) used to stimulate muscles for an array of conditions.

1.2 Indications for Use

NeuroMuscular Stimulation (NMS), also commonly referred to as Electrical Muscle Stimulation (EMS) is the use of electrical stimulation on muscle groups to contract and re-educate muscles. Some of the uses of NMS are as follows:

1) The Prevention or Retardation of Muscle Disuse Atrophy: Muscle disuse atrophy is a reduction in muscle tone and size due to prolonged impairment or joint immobility from surgery or injury. The use of NMS to contract the muscles assists in prevention of disuse atrophy.

2) Relaxation of Muscle Spasms: Muscle spasms often occur in areas of localized pain and tenderness. Stimulation is used to fatigue the spasmodic muscle.

3) Maintaining and Increasing Range of Motion

4) Muscle Reeducation

5) Increasing Local Blood Circulation: Rhythmic muscle contraction helps improve local blood circulation.

6) Immediate Postsurgical Stimulation of Calf Muscles to Prevent Venous Thrombosis. The use of NMS or EMS to increase local blood circulation assists in the prevention of venous thrombosis.

2. Introduction BioStim® NMS2

2.1 Precautions should be taken when stimulation is used;

• After recent surgical procedure where muscle contraction may disrupt the healing process.

 \bullet After an acute trauma or fracture where there is a tendency to hemorrhage.

• Over the menstruating uterus.

• Where the sensory nerve damage has caused the loss of normal skin sensation.

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

2.2 Caution:

NMS or EMS Devices should only be used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. Dependent upon government regulation, this device may or may not require a medical prescription. Federal law (USA) restricts the sale by, or on the order of, a physician so licensed by the State. Keep out of reach of children.

2.3 Adverse Reactions:

Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrically conductive medium. The irritation can usually be reduced by using an alternative conductive medium, or alternate electrode placement. Improper use of stimulation may result in skin irritation and burns beneath the electrodes. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

2.5 Contraindications:

1) Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

2) NMS or EMS devices should not be applied over, or in proximity to, cancerous lesions.

3) NMS devices should not be used while driving, operating machinery or during any other activity in which involuntary muscle contraction may put the user at undue risk of injury.

4)Stimulation should not be applied over the carotid sinus. Severe spasm of the laryngeal and/or pharyngeal muscles may occur when electrodes are placed over the neck or mouth. (These contractions may be strong enough to close the airway or cause difficulty in breathing.)

5)Stimulation should not be applied transcerebrally (through the head).

6) Adequate precaution should be taken when treating patients with suspected heart problems or epilepsy. Caution should be exercised in the transthoracic application of EMS devices so that the introduction of electrical current into the heart does not cause arrhythmias. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc. Persistent use of stimulation in the presence of skin irritation may be injurious.

7)The safety of electrical stimulation for use during pregnancy has not been established.

8)The long-term effects of chronic electrical stimulation are unknown.

9) EMS devices should be kept out of the reach of children.

10) Simultaneous connection to RF surgery equipment can cause a burn.

11) Operation near (e.g. 1m) short wave or micro wave therapy equipment can change the output values of the stimulator.

12) This equipment may be affected by electromagnetic interference. Also, other electrical equipment in close vicinity may be affected by the BioStim NMS. If such effects are suspected either switch off the offending equipment or increase the distance between the affected equipment and that suspected of causing the interference or shorten connecting leads.

3. Technical Data

- 2 Leadwires (4 pins)
- 4 electrodes (pads)

Accessoires

- 1 Instruction Booklet
- 4 AA Batteries
- 1 Carry Pouch

Only use accessories, electrodes, leadwires and batteries approved by BioMedical Life Systems, Inc.

Size	3.9"x2.6"x1.3" (99mmx65mmx33mm)				
Weight	8 oz (226g)				
Power supply	4 AA Batteries, type LR6				
Channels	Dual				
Waveform	Symmetrical, biphasic square (SYM) and Asymmetrical, biphasic square (ASYM)				
Pulse Rate	Adjustable 1 - 120 Hz (Hertz), pulses/sec				
Pulse Width	Adjustable 50 - 400 µS (microseconds)				
Ramp On	0-99 seconds				
Ramp Off	0-99 seconds				
On Time	0-99 seconds				
Off Time	0-99 seconds				
Delay	0-99 seconds				
Patient Timer	0-99 minutes				
Modes	1.Constant 2. Cycled 3. Reciprocal (adjustable)				
Therapies	8 Preprogrammed (fixed)				
Intensity/Output Voltage	Continuously adjustable from 0-120mA peak (0-60V) +/- 10%				
Tolerance	All parameters +/- 2% unless otherwise noted				
Data recorded across a 500 OHM load resistance					

Guidance and Manufacturer's declaration-							
elec	electromagnetic emissions						
This device is in	tended for use in	the electromagnetic					
environment spe	cified below. The	e customer or the user					
should assure t	hat it is used in s	uch an environment.					
Emissions Test	Compliance	Electromagnetic					
		environment-					
	<u> </u>	guidance					
RF emissions	Group 1	I his device uses RF					
CISPR11		internal function					
		Therefore its PE					
		emissions are very low					
		and are not likely to					
		cause any interference					
		in nearby electronic					
		equipment.					
RF Emission	Class B						
CISPR 11		This device is suitable					
Harmonic	Not	for use in all					
emissions IEC	applicable	establishments,					
61000-3-2		including domestic					
Voltage		establishments					
fluctuations	fluctuations and those directly						
Flicker emissions	Complies	connected to the public					
IEC 61000-3-3		low-voltage power					
	supply network that						
	supplies buildings for						
		domestic purposes.					

This device was not tested for IMMUNITY to ELECTROMAGNETIC DISTURBANCES.

4. Modes Explained

4.1 Programmable Mode Starting Parameters:

There are 3 Programmable Modes on the BioStim® NMS 1. Constant; 2 Cycled; 3 Reciprocal

• Each of the three programmable modes has starting parameters, however the parameters may be adjusted by the user.

Programmable settings may be customized and saved.
 (All times measured in seconds unless athemains and

(All times measured in seconds unless otherwise specified.)

Mode	Wavefor (PR= Pulse \	m Paran Rate; P Vidth)	Timing Options	
1. Constant (CONST)	Asymme S	trical Bip Square	N/A	
	PR 120Hz	PW	50µS	

Use of the Constant Mode or a Pulse Rate greater than 60Hz with a symmetrical biphasic square waveform should be used for the relaxation of muscle spasms only. Use of constant stimulation and/or rates above the normal physiological range (e.g., greater than 60Hz) could lead to rapid onset of muscle fatigue, making the device less effective in producing repeated forceful muscle contractions.

2. Cycled	Syr	nmetrica	l Biphas	Ramp	2/2	
					On/Off	
	PR	35Hz	PW	300µS	On Time	10
					Off Time	20
In the CYCLED mode; both Channel 1 and Channel 2 cycle						
		sim	ultaneo	usly.		
 Reciprocal (RECIPR) 	Symmetrical Biphasic Wave				Ramp On/Off	2/2
(,	PR	35Hz	PW	300µS	On Time	10
					Off Time	20
In the RECIPR mode, Channel 1 and Channel 2 alternate; (Channel 1 is on while Channel 2 is off).						

4.2 Pre-Set Therapy Mode Parameters:

There are 8 Pre-Set Therapies in the BioStim® NMS².

Note: Settings in the following THERAPY modes are FIXED and cannot be changed. If custom settings are needed, please see Programmable Modes Explained; (Section 9)

					• •	
Therapy	Stimulation Pattern;			Timing Options		
	(Const, Cycled or Reciprocal)				(In Seconds	;)
Therapy	Cycled				Ramp On/Off	2/2
1	Symr	netrical	Biphasi	c Wave	On Time	10
	PR	35Hz	PW	300µS	Off Time	20
Therapy		C	ycled		Ramp On/Off	2/2
2	Asym	metrica	l Biphas	sic Wave	On Time	10
	PR	35Hz	PW	400µS	Off Time	20
Therapy	Cycled				Ramp On/Off	2/2
3	Symmetrical Biphasic Wave				On Time	10
	PR	50Hz	PW	180µS	Off Time	20
-	1					2/2
Therapy	Cycled				Ramp On/Off	2/2
4	Symr	netrical	Biphasi	c Wave	On Time	5
	PR	20Hz	PW	250µS	Off Time	10
					•	
Therapy		Cor	nstant	Ramp On/Off	0	
5	Symr	netrical	Biphasi	c Wave	On Time	0
	PR	10Hz	PW	50µS	Off Time	0

Therapy		Constant			Ramp On/Off	0
6	Asym	metrical	Biphas	ic Wave	On Time	0
	PR	10Hz	PW	200µS	Off Time	0
Therapy	Cycled			Ramp On/Off	1/0	
7	Symr	netrical	Biphasi	On Time	5	
	PR 35Hz PW 400µS			Off Time	5	
Therapy		Cycled Symmetrical Biphasic Wave			Ramp On/Off	2/2
	Symr				On Time	10
	PR 35Hz PW 50µS			Off Time	20	

5. Batteries

5.1 Batteries

In order to maintain the functional operation of the BioStim NMS², the batteries will have to be changed periodically. The device is supplied with 4 AA Alkaline batteries. When batteries are running low, a battery image will appear and flash on the bottom right hand corner of the LCD display screen. When this image appears, the batteries should be changed to ensure maximum performance. If you have saved programs into the device, they will remain stored even when the batteries are changed.

To insert batteries:

• Before opening the battery compartment, check sure that the device is switched off.

- Flip open the battery compartment cover.
- Remove the batteries from the compartment. Gently insert the new batteries by matching the +/- end of each battery with the +/- symbol found inside the battery compartment.
- Flip the battery cover to the closed position.
- Remove the batteries if you do not plan to use the device for long periods of time, otherwise leakage and damage to the device may occur.
- Dispose of batteries in a proper manner.

6. Electrodes and Leadwires

• The "leadwires" are the 48" wires provided with your device.

• The "electrodes" are the four adhesive pads provided with your device.

• The leadwires and electrodes should be replaced periodically. They are consumable supplies and are not covered under the device warranty.

• Only use accessories approved by BioMedical Life Systems, Inc. Use of non-approved accessories may affect the performance of the device, cause injury and void the device warranty.

• The electrodes are disposable and should be replaced routinely when they start to lose their adhesive properties.

• Replacement electrodes and leadwires should be reordered through the dealer who supplied the device.

6.1 Connect electrodes and lead wires

1) Make sure the device is turned off, if the device is on, press the button labeled "On/Off" one time until the LCD display is blank.

2) Insert the leadwires into the sockets in the top of the BioStim NMS2 device marked "Ch1 and/or Ch2". If only two electrodes are needed, you may insert the wire into only one Ch.

3) Attach the electrodes to the leadwires following the instructions on the electrode packaging. At least 2 electrodes from the same channel must be placed on the body for stimulation to begin.

4) Check to ensure that no metal is exposed from the pin of the leadwire where it connects to the electrode.

5) Attach the electrodes to the body per your physicians instructions.

7. Graphic Symbol Definitions



Refer to operating instructions



An IEC 601-1 safety standard (type BF)



We herewith declare that the abovementioned product meets the provisions of the Medical Device .

7.1 BioStim® NMS² Button Descriptions

Button Symbol		Button Function
1	0	ON/OFF
2/3	(†	AMPLITUDE CONTROL
4/9	(\mathbf{b})	INCREASE VALUE/ DECREASE VALUE
5	\exists	MODE SELECT
6	E	ENTER
7	<u> </u>	SETTING INFORMATION KEY
8	Ø	PULSE RATE/PULSE WIDTH & WAVEFORM SELECT
10	0	TIMER KEY



Basic Button Functions:

Button 1 "On/Off" Key: This button is used to turn the device on or off.

Button 2 & 3 "Amplitude Control" Keys: These buttons are used to begin or adjust the intensity flow of energy through the lead wires to the electrodes. Button (2) Controls Channel 1 amplitude and button (3) Controls Channel 2 amplitude. Each Channel's intensity is controlled independently. You may use only one channel at a time or both simultaneously.

Button 4 & 9 "Increase Value/Decrease Value" Keys: These keys are used to increase or decrease numeric values of the parameters such as pulse rate, pulse width, waveform and timing options (RAMP TIME, ON TIME, OFF TIME & DELAY).

Button 5 "Mode Select" Key: This key is used to change the mode on the device.

Button 6 "Enter": This key is used to accept a value.

Button 7 "Setting Information Key": This key is used to view the timing options (RAMP TIME, ON TIME, OFF TIME & DELAY) of a Mode or Therapy without changing the values.

Button 8 "Pulse Rate/Pulse Width & Waveform Select" Key: This key is used to select the Pulse Rate, Pulse Width, or Waveform in order to change the values.

Button 10 "Timer" Key: This key is used to select the Patient Timer in order to set the value.

8. Programming Instructions

The BioStim NMS² features three adjustable Modes; (CONSTANT, CYCLED and RECIPROCAL (RECIPR) and eight preset fixed therapies (THERAPY 1-8) comprised of commonly used Constant, Cycled or Reciprocal settings. If none of the eight preset therapies meet the user's needs, the three programmable modes may be used to create and store custom programs. The BioStim® NMS² has a timer, Patient Lock and Patient Compliance Monitoring functions.

8.1 Toggling through the Modes:

1) Turn the device on or (1) ("On/Off" Key

2) Choose a Mode by pressing the "Mode" Key (5)

repeatedly until the mode or therapy you wish to use is displayed on the screen.

The following diagram demonstrates the order in which pressing the "Mode" Key (5) \bigcirc scrolls through the device modes.



Once the desired mode is displayed on the screen you may begin stimulation by pressing the (2) $\stackrel{\frown}{\smile}$ or (3) $\stackrel{\frown}{\multimap}$ keys. The (2) $\stackrel{\frown}{\multimap}$ key controls the amplitude of Channel 1 and the (3) $\stackrel{\frown}{\multimap}$ key controls the amplitude of Channel 2.

In CONST, CYCLED and RECIPR modes you may adjust the settings before beginning stimulation.

8.2 Defining Timing Options; RAMP TIME, ON TIME OF TIME & DELAY

The timing options include the Ramp On, Ramp Off, On Time, Off Time & Delay and can be modified in the Cycled or RECIPR modes (only). The device will hold the custom settings until changed or until the device is reset to factory settings. **<u>RAMP ON:</u>** Is the amount of time in seconds the device itensity ramps up from the OFF Time to the maximum intensity of the ON Time in each cycle.

RAMP OFF: Is the amount of time in seconds the device intensity ramps down from the ON Time to the OFF Time in each cycle.

Special Notes Regarding RAMP ON/OFF Times

- In the BioStim® NMS² the RAMP ON can be different from the RAMP OFF value in the cycle.
- The RAMP ON and RAMP OFF values set to both Channel 1 and Channel 2. ON TIME: The total amount of time seconds in each cycle that the device intensity is on, including the ramp times.

Special Notes Regarding ON TIME:

- Once the RAMP ON and RAMP OFF values have been set, the device will not allow the user to set a ON TIME value lesser than the sum of the RAMP ON and RAMP OFF values, as the ON TIME is the total time the device intensity is on in the cycle, including the ramp times.
- Note: The ON TIME value is set independently for Channel 1 and Channel 2 and may be a different value for Channel 1 than Channel 2.
- If different ON TIME values are set for Channel 1 and Channel 2 in a CYCLED program, the difference between the Channel 1 and Channel 2 ON TIME will be automatically added or subtracted from the Channel 2 OFF TIME as the total cycle times for Channel 1 and Channel 2 need to be the same in the CYCLED mode. In the RECIPR mode, the total cycle time does not need to be the same, therefore, the user may set different ON TIME values for Channel 1 and Channel 2 without the device deducting the difference from the OFF TIME of Channel 2.

OFF TIME: The amount of time in seconds that the device intensity is off in each cycle.

DELAY: The amount of time in seconds between the begininning of Channel 1 cycle and beginning 2 cycle. (DELAY is available in the CYCLED mode only). The DELAY can be adjusted from 1-99 seconds.

Note: If a "DELAY" value is set in the CYCLED mode, the number of seconds set for the DELAY will be automatically deducted from the OFF TIME of Channel 2, as both Channel 1 and Channel 2 total cycle times must be the same. The following is an example of a Cycled Program with a DELAY time of 5 seconds.

	Channel 1	Channel 2
Ramp on	2.0 sec.	2.0 sec.
Ramp off	2.0 sec.	2.0 sec.
On time	20 sec.	10 sec.
Off time	10 sec.	15 sec.
Delay	N/A	5 sec.
TOTAL	35 sec.	35 sec.



8.3: Changing Timing Options; RAMP TIME, ON TIME OFF TIME & DELAY

Step 1: Turn the device OFF and then back ON by pressing the "ON/OFF" Key (1) O

Step 2: Press the "Mode Key" (5) ⁽³⁾ repeatedly until either "Cycled or "RECIPR" appear on the screen.

Step 3: Press the +(4) key until the numeric value for RAMP ON flashes on the screen.

Step 4: Increase or decrease the value of the flashing number by pressing the +(4) $\xrightarrow{}$ and/or -(9) $\xrightarrow{}$ keys.

Step 5: Press the "Enter" (6) key to accept the set value.

Device then moves to the next adjustable timing option displayed in the diagram (below), beginning with RAMP ON.

Step 6: Continue moving through each value, changing the value by pressing the +(4) \xrightarrow{f} Aand -(9) $\xrightarrow{}$ keys and/or accepting the value by pressing the "Enter" Key (6) $\stackrel{\frown}{}$ until there are no blinking values.

Step 7: (Optional) To review the timing option settings without changing them, use the "Info" Key (7) \bigcirc to scroll through the settings.

Step 8: You may begin stimulation by pressing the (2) and/or (3) keys.



8.4 Changing PR (Hz), PW (μ S) and Waveform Values

To change the "PR" (Pulse Rate Value, measured in Hz), PW (Pulse Width (measured in μ S) or Waveform (SYM = Symmetri cal Biphasic or ASYM = Asymmetrical Biphasic Waveform)

Step 1: Turn the device OFF and then back ON by pressing the "ON/OFF Key" (1) O

Step 2: Press the "PR/PW" (8) Key repeatedly until the parameter you desire to change is flashing

Step 3: Use the +(4) $\xrightarrow{(+)}$ and -(9) $\xrightarrow{(-)}$ keys to increase/de crease or change the value.

Step 4: You must press the "Enter" key (6) ^(C) to accept the value. To change another parameter, repeat steps 2-4.

Note: The stimulation cannot begin if any value on the LCD screen is blinking. If a value is blinking on the screen, press the "Enter" Key (6) ^(E) until there are no blinking values.



8.5 Patient Timer

The BioStim NMS² device has a patient Timer feature. When the timer is enabled, the device counts down in minutes. The device shuts off when the time runs out. If the timer is not set, the device will continue to run until the "ON/OFF" key (1) O is pressed, or if the device is idol (with no intensity settings) for 7 consecutive minutes.

Step 2: Press the "Timer" Key (10) (2) until a small clock appears on the display and "0" min is flashing.

Step 3: Immediately press the +(4) $\xrightarrow{(+)}$ and -(9) $\overleftarrow{(+)}$ keys to increase/decrease the number of minutes. If the timer stops flashing before the desired value is set, press the "Timer" key (10) O again until the time blinks, and resume pressing the +(4) $\xrightarrow{(+)}$ and -(9) $\overleftarrow{(+)}$ keys until the desired time is displayed.

Step 4: Press the "Enter" key (6) ^(E) to accept the value. The timer is now set.



8.6 Patient Lock

The BioStim NMS² has a Patient Parameter Lock Feature. When activated, this feature locks all of the displayed settings except the Intensity Controls (mA), ON/OFF capabilities and Timer feature.

The Patient Lock prevents the user from accidently changing the physician settings, however it still allows the user to perform basic functions such as controlling the intensity, setting the timer and turning the device on and off.

To Turn On the Patient Lock Feature:

Step 1: Select the desired settings

Step 2: If any values are blinking on the screen press the "Enter Key" (6) ^(E) until all values are accepted and nothing is blinking

or Turn the device OFF and back ON by pressing the "ON/OFF" Key (1) $\textcircled{\sim}$

Step 3: To activate the lock hold down both the "ENTER" E (6) key and the+ (4) A key simultaneously for approximately 3 seconds until the Clock symbol flashes on the LCD screen. The Patient Lock Feature is now activated.

To Turn Off the Patient Lock Feature (unlock):

Press and hold both the ENTER E (6) © and the -(9) simultaneously for approximately 3 seconds. Hold the buttons until you see the Clock symbol on the LCD stop flashing and a double digit number appears below the clock (This is the Patient Compliance Meter read-out. See Section 8.7 Patient Compliance Meter.) The Patient Lock Feature is now deactivated.

8.7 Patient Compliance Meter

The Patient Compliance Meter records usage time in hours beginning from the first time the device amplitude is turned on and provides stimulation to the user. It records and stores the usage time in hours (up to 1099 hours). The Patient Compli ance meter does not need to be "set" as it begins recording automatically.

To view the amount of hours the patient has used the device:

Step 1: Turn on device by pressing the "ON/OFF" Key (1) (1)

Step 2: If any values are blinking on the LCD screen press the "Enter Key" (6) ^(C) until all values are accepted and nothing is blinking or Turn the device OFF and back ON by pressing the "ON/OFF" Key (1) ^(C)

Step 3: Press and hold down both the "Timer" Key (10) (1) and the Channel 2 intensity key (3) (1) in the "+" direction for approximately 3 seconds. When done correctly, the LCD will "blank out" except for the clock symbol, with a 2 digit number underneath, and if applicable, bars on the left hand side of the screen will appear.

Below the Clock Symbol (D) the number of hours the device has been used is displayed. Once 99 hours has been reached, a bar next to the "1" on the left Amplitude Display (F) will appear. Each bar indicates 100 hours of use. The maximum amount of time that will be displayed is 1099 hours. The device does not "reset" back to "00" after the maximum time is reached. The diagram (below) indicates the device has been used for 566 hours.



9. Programmable Modes Explained

9.1 Constant Stimulation:

CONSTANT is a mode which delivers a "Constant" output of the set PR, PW, and Waveform. <u>In this mode, there are no timing options</u>. (RAMP ON, RAMP OFF, ON TIME, OFF TIME and DELAY) In this mode, the device will function similar to a T.E.N.S. unit.

Note: Use of the Constant Mode or a Pulse Rate greater than 60Hz with a symmetrical biphasic square waveform should be used for the relaxation of muscle spasms only. Use of constant stimulation and/or rates above the normal physiological range (e.g., greater than 60Hz) could lead to rapid onset of muscle fatigue, making the device less effective in producing repeated forceful muscle contractions.

9.2 Setting the CONSTANT (CONST) Mode

Step 1: Attach leadwires to Channel 1 (CH1) and if needed to Channel 2 (CH2) (Refer to section 6.1 Connect electrodes and lead wires)

Step 2: Attach electrodes to the leadwires by following the instructions on the electrode packaging.

Step 3: Attach electrodes to the body per the instructions given by the prescribing practitioner.

Step 4: Turn device on by pressing the "ON/OFF" Key (1) (1)

Step 5: Press the "Mode" Key (5) (1) until "CONST" appears on the screen. The last settings used are displayed. If the device was never used, the factory settings are displayed. To refer to factory settings see section: 4.1 (Programmable/ Adjustable Mode Starting Parameters).

Step 6: (Optional) To change the Hz, μ S or waveform; See section 8.4 (Changing PR (Hz), PW (μ S) and Waveform Values)

Step 7: (Optional) To set the Patient Timer see section 8.4 (Patient Timer). If the timer is not set, the device will continue to run until the "ON/OFF" key (1) O is pressed, or if the device is idol (with no intensity settings) for 7 consecutive minutes.

Step 8: To begin stimulation; increase or decrease the intensity of each Channel by pressing the (2) $\stackrel{\frown}{\longrightarrow}$ or (3) $\stackrel{\frown}{\longrightarrow}$ buttons in the "+" direction.

9.3 Cycled Stimulation:

CYCLED Stimulation is a mode which delivers the set Pulse Rate (Hz) Pulse Width (US) and Waveform (ASYM or SYM) in repeating cycles comprised of "timing options" (RAMP ON, RAMP OFF, ON TIME, OFF TIME and DELAY) in order to elicit repeated muscle contractions and rest periods.

In the CYCLED mode both Channel 1 and Channel 2 output the set cycle of timing options simultaneously, hence, the total Cycle time for Channel 1 and Channel 2 must be the same. When ON TIME/OFF TIME values are different between Channel 1 and 2, or when a DELAY value is set, the device automatically calculates and adjusts the OFF TIME of Channel 2 to ensure the total Cycle times of Channel 1 and 2 remain the same. (See Section 8.2 Defining Timing Options; RAMP TIME, ON TIME, OFF TIME & DELAY for clarification)



9.4 Setting the CYCLED Mode

Step 1: Attach leadwires to Channel 1 (CH1) and if needed Channel 2 (CH2) (Refer to section 6.1 Connect electrodes and to lead wires) Step 2: Attach electrodes to the leadwires by following the instructions on the electrode packaging. **Step 3:** Attach electrodes to the body per the instructions given by the prescribing practitioner.

Step 4: Turn device on by pressing the "ON/OFF" Key (1) (1)

Step 5: Press the "Mode" Key (5) until "CYCLED" appears on the screen. The last settings used are displayed. The factory settings are displayed if never used. To refer to factory settings see section: 4.1 (Programmable/Adjustable Mode Starting Parameters). To view the Timing options without changing them, press the "Info" Key (7) repeatedly to scroll through the settings. To use the current settings, proceed to Step 9. To change the settings proceed to Step 6.

Step 6: (Optional) To Change the Timing options refer to section (s) 8.2-8.3 (Changing the Timing Options; RAMP TIME, ON TIME OFF TIME & DELAY)

Step 7: (Optional) To change the Hz, μ S or waveform; See section 8.4 (Changing PR (Hz), PW (US) and Waveform Values)

Step 8: (Optional) To set the Patient Timer see section 8.5 (Patient Timer). If the timer is not set, the device will continue to run until the "ON/OFF" key (1) O is pressed, or if the device is idol (no intensity settings) for 7 consecutive minutes.

Step 9: To begin stimulation; increase or decrease the intensity of each Channel by pressing the (2) $\stackrel{\frown}{\longrightarrow}$ or (3) $\stackrel{\frown}{\longrightarrow}$ buttons in the "+" direction.

The device will hold the custom settings until changed or until the device is reset to factory settings. (See Section 8.8)

9.5 Reciprocal Stimulation (RECIPR)

Reciprocal Stimulation displayed as (RECIPR) is a mode which delivers the set Pulse Rate (Hz) Pulse Width (US) and Waveform (ASYM or SYM) in repeating cycles comprised of "timing options" (RAMP ON, RAMP OFF, ON TIME, OFF TIME and DELAY) in order to elicit repeated muscle contractions and rest periods.

In the RECIPR mode Channel 1 and Channel 2 cycles alternate. Therefore, Channel 1 and Channel 2 timing options can be set completely independent of one another.



9.6 Setting the Reciprocal (RECIPR) Mode

Step 1: Attach leadwires to Channel 1 (CH1) and if needed to Channel 2 (CH2) (Refer to section 6.1)

Step 2: Attach electrodes to the leadwires by following the instructions on the electrode packaging.

Step 3: Attach electrodes to the body per the instructions given by the prescribing practitioner.

Step 4: Turn device on by pressing the "ON/OFF" Key (1) (1)

Step 5: Press the "Mode" Key (5) (3) until "RECIPR" appears on the screen. The last settings used are displayed. The factory settings are displayed if never used. To refer to factory settings see section: 4.1 (Programmable/Adjustable Mode Starting Parameters). To view the Timing options without changing them, press the "Info" Key (7) (1) repeatedly to scroll through the settings. To use the current settings proceed to Step 9. To change the settings, proceed to Step 6.

Step 6: (Optional) To Change the Timing options refer to sec tion(s) 8.2-8.3 (Changing the Timing Options; RAMP TIME, ON TIME OFF TIME & DELAY)

Step 7: (Optional) To change the Hz, μ S or waveform; See section 8.4 (Changing PR (Hz), PW (US) and Waveform Values)

Step 8: (Optional) To set the Patient Timer see section 8.5 (Patient Timer). If the timer is not set, the device will continue to run until the "ON/OFF" key (1) O is pressed, or if the device is idol (with no intensity settings) for 7 consecutive minutes.

Step 9: To begin stimulation; increase the intensity of each Channel by pressing the (2) \bigcirc or (3) \bigcirc buttons in the "+" direction. You may also decrease the intensity at any time by pressing the (2) \bigcirc or (3) \bigcirc buttons in the "-" direction.

10. Using THERAPY Modes 1-8

There are eight pre-programmed therapies to choose from in the BioStim NMS2 device. These therapies are "fixed" and cannot be altered. To view the settings refer to section 4.2 (Pre-Set Therapy Mode Parameters).

The Pre-Set Therapies are designed for ease of use. The most common CONSTANT, CYCLED, and RECIPROCAL settings are preprogrammed into the device and labeled THERAPY 1-8. If adjustments need to be made to the settings, the Programma ble Modes will need to be used instead of a pre-set Therapy. (See Sections 9-9.6 Programmable Modes Explained).

STEP 1: Turn device on by pressing the "ON/OFF" Key (1) (1)

STEP 2: Press the "Mode" Key (5) (5) repeatedly to scroll through the different Mode Selections; CONST., CYCLED, RECIPR., THERAPY1, THERAPY 2, THERAPY 3, THERAPY 4, THERAPY

5,THERAPY 6, THERAPY 7, and THERAPY 8 until the desired THERAPY is displayed on the LCD Screen.

STEP 3: (Optional) To set the Patient Timer see section 8.5 (Patient Timer). If the timer is not set, the device will con tinue to run until the "ON/OFF" key (1) is pressed, or if the device is idol (with no intensity setting) for 7 consecutive minutes.

STEP 4: Increase the Intensity using buttons (2) $\stackrel{\sim}{\sim}$ and/or (3) $\stackrel{\sim}{\sim}$ to begin stimulation.

11. Malfunctions

Should any malfunctions occur while using this device, check:

• Whether the leadwires and electrodes are correctly connected to the device. The leadwires should be inserted firmly into the device sockets.

• For possible damage to the leadwires. Change the leadwires if any damage is detected.

Do not attempt to repair a device yourself!

Opening the device case voids the warranty. Please contact the dealer from whom the device was purchased. If they are unable to assist you, please contact:

BioMedical Life Systems, Inc. 1954 Kellogg Avenue Carlsbad, California 92008-6581 USA Tel: (1) (800) 726-8367



BioMedical Life Systems, BV Postbus 6 1800 AA Alkmaar, Netherlands Tel: 31 72 567 2098



12. Safety and Technical Checks

Once a year, a maintenance check should be performed on the device as follows:

- Visually check the exterior case of the device for damage.
- Visually check the input and output sockets for damage.
- Visually check the device for clarity of reading instructions and indicator decals.
- Visually check that the symbols of the LCD are operating correctly.
- · Visually check leadwires and electrodes for damage

This device MUST only be serviced by the manufacturer.

To reorder any accessories or supplies, contact your dealer.

13. Maintenance and Care

- The case housing is made of ABS plastic and can be cleaned with isopropyl alcohol.
- NOTE: Do not smoke or work with an open flame (for example, candles, etc.) when working with flammable liquids! .
- See electrode packaging for instructions on maintenance and care.
- Store device and accessories in a cool dry place.

14. Warranty

LIMITED WARRANTY (USA only, unless otherwise noted)* BioMedical Life Systems, Inc. promises to the original consumer purchaser to repair or, at the option of BioMedical Life Systems, Inc., to replace any NeuroMuscular Stimulator which malfunction is or proves defective in materials or workmanship under nemal use during the period of the Warranty. During this time, BioMedical Life Systems, Inc. will provide all labor and parts necessary to correct such defects or malfunctions free of charge. If the product is no longer available, BioMedical Life Systems, Inc. reserves the right to substitute a comparable product. The consumer-purchaser is responsible for all shipping charges when returning the device to the manufacturer or designated service facility.

EXCLUSIONS

This warranty shall not apply to damage resulting from failure to follow these Instructions, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as rechargeable batteries, electrodes, leadwires, and conductive gel. These items can be provided by your dealer, but costs for repair or replacement will be the responsibility of the consumer-purchaser. BioMedical Life Systems, Inc. shall not be liable for incidental or consequential damages resulting from the sale or use of the device. In the USA, some states do not allow the exclusion or limitation of incidental or consequential damages, or do not allow limits on how long an implied warranty lasts, so the above limitation may not apply to you.

NO OTHER WARRANTIES

This limited warranty is the only express warranty given by BioMedical Life Systems, Inc. Implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth below. This warranty gives you specific legal rights, and you may also have rights which vary from state to state. If the device case is opened or tampered with in any way, all warranty coverage is void.

*In the USA, unless otherwise indicated, the limited Warranty is three years. Outside the USA, please check with your distributor to ascertain the "Limited Warranty Period."